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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,356	07/23/2001	Ioannis Pallikaris	10781/9	3390

7590 02/27/2003

VINCENT J. GNOFFO  
BRINKS, HOFER, GILSON & LIONE  
455 N. CITYFRONT  
NBC TOWER, SUITE 3600  
CHICAGO, IL 60611

EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/911,356

Applicant(s)

PALLIKARIS ET AL.

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,7,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is improper because it states "at least one of" but all the choices are linked together.

Claim 7, line 25, "the ring" lacks antecedent basic.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 14-15 are rejected under 35 U.S.C. 102 (e) as being anticipated by Amano (U.S. 6,506,198).

Regarding claims 1 and 3, Amano shows in figures 1, 2, a mechanical device (1) includes a separator (21a), wherein the device can preserve the separated epithelial layer without

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rupturing the disk and without substantial epithelial cell loss; wherein the separator (21a) is not sharp enough to excise corneal tissue.

Regarding claims 2 and 4, Amano shows in figures 1, 2, wherein a ring (31) seats on the eye, wherein a separator support (21a) fits in the groove (fig. 3, items 22a, 23a) and an oscillation device (12) provides motion and vibration to the separator (21a); wherein the separator (21a) is not sharp enough to excise corneal tissue.

Regarding claims 5 and 6, Amano shows in figures 1, 2 and col. 7 lines 4-21, wherein a travel of the separator (21a) is controlled to produce an epithelial disk hinged to the border of the separation.

Regarding claims 7 and 8, Amano shows in figures 1, 2, wherein the ring (31) includes a circumferential groove (fig. 3 items 22a, 23a) on the side of the eye and suction (3) is applied to the circumferential groove to ensure stable mounting of the ring (31).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12 are rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Bair et al (6,126,668) .

Regarding claim 9, Amano discloses the invention substantially as claimed. However, Amano does not disclose the separator oscillates with frequency ranging from about 10 Hz to about 10,000 Hz . Bair et al teaches the separator oscillates with frequency ranging from about

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8,000-15,000 rpms, which is about 133 Hz-250 Hz (col. 13 lines 8-14). It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Amano by adding the separator oscillating with a frequency ranging from about 8,000-15,000 rpms, which is about 133 Hz-250 Hz as taught by Bair et al in order to produce an optimal rate of oscillation for the cutting instrument.

Claims 10-12 are rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Bair et al (6,126,668) and further in view of Tanne (4,665,914).

Regarding claims 10-12, Amano in view of Bair et al disclose a device having all limitations substantially as claimed. However, the combination fails to disclose the separator oscillation provided by electromagnetic forces or piezoelectric forces on the separator. Tanne (see col. 5 lines 35-68) teaches the separator oscillation provided by electromagnetic forces or piezoelectric forces on the separator.

It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify the combination of Amano in view of Bair et al by adding the separator oscillation provided by electromagnetic forces or piezoelectric forces on the separator because this would have been merely an alternate and analogous way to produce the oscillation in the modified Amano device.

Claim 13 is rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Ruiz et al (5,133,726).

Regarding claim 13, Amano discloses the invention substantially as claimed. However, Amano does not disclose the device includes rotating gears. Ruiz et al teaches a corneal shaping device that oscillates by the use of rotating gears (figures 1, 10). It would have been obvious to

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one having ordinary skill in the art at the same time the invention was made to modify Amano by adding the oscillation by rotating gears as taught by Ruiz because this would have been merely an alternate and analogous way to produce the oscillation in the modified Amano device.

Claims 16-17 and 21-23 are rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Ruiz et al (5,133,726) and further in view of Schilk(4,659,584).

Regarding claims 16-17 and 21-23, Amano in view of Ruiz et al disclose a device having all limitations substantially as claimed. The combination also discloses at least the device include the rotating gears. However, the combination fails to disclose the device further includes a rotating drum. Schilk (see figure. 5 col. 2 lines 1-15) teaches the device include the rotating drum.

It would have been obvious to one having ordinary skill in the art at the same time the invention was made in view of Schilk to modify the combination of Amano in view of Ruiz et al by adding the device include the rotating drum for the purpose of allowing the epithelial disk to roll on the drum.

Claims 18-20 are rejected under 35 U.S.C 103 (a) as being unpatentable over Amano (6,506,198) in view of Schilk (4,659,584) and further in view of Dan et al (5,462,739).

Regarding claims 18-20, Amano in view of Schilk disclose a device having all limitations substantially as claimed. The combination also discloses at least the device include the rotating drum. Dan et al (see col. 5 lines 34-67 and col. 6 lines 51-56) teaches the drum is coated with at least one of hydrating substrate and at least one of hydrating substrate is selected from biocompatible hydrogels.

It would have been obvious to one having ordinary skill in the art at the same time the invention was made in view of Dan et al to modify the combination of Amano in view of Schilk by adding the drum coated with at least one of hydrating substrate in order to increase permeability at the drum and to enhance the substrate penetration into the eye.

***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,215,104 to Steinert	U.S. Pat. No. 5,312,413 to Eaton et al
U.S. Pat. No. 5,997,559 to Ziemer	U.S. Pat. No. 5,108,412 to Krumeich et al
U.S. Pat. No. 5,554,155 to Awh et al	

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen  
Examiner  
Art Unit 3731

vn *JH*  
February 24, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700